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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,621

03/10/2004

Edward I. Wulfman

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EXAMINER

BHATIA, AARTI

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/798,621	<b>Applicant(s)</b> WULFMAN ET AL.	
	<b>Examiner</b> Aarti Bhatia	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/25/2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9,10,16-19,24,27-29,32,56 and 58-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,10,16-19,24,27-29,32,56 and 58-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is the third Office Action based on the 10/798,621 application filed on 3/10/2004.

Claims 1-7, 9-10, 16-19, 24, 27-29, 32, 56, and 58-65, as amended on 11/25/2008, are currently pending and have been considered below.

#### ***Response to Amendment***

1. The double patenting warning has been withdrawn in view of the amendments made by the Applicant to co-pending application 10/798,618.

#### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,398,755 to Belef et al. in view of US 2002/0007190 to Wulfman et al. or in view of U.S. Patent No. 6,565,588 to Clement et al.

Belef teaches an interventional catheter assembly (4) comprising: an operating head (32) coupled to a drive shaft and a drive assembly (22) for rotation and a catheter system mounted for axial translation at a proximal end with a control pod (6) and communicating at a distal end with the operating head; and a control pod housing operational components for selectably rotating the operating head.

Belef fails to teach wherein the operating head is adjustable between two different operating diameters and a selection switch that allows an operator to select between two different operating head diameters.

Wulfman and Clement teach catheter assemblies that have adjustable diameters. Further, Wulfman teaches a sliding actuator in communication with the drive system. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter assembly of Belef with the adjustable diameter switch of Wulfman or Clement to facilitate translation and navigation of the device through various lumens (abstract of both Wulfman and Clement).

Belef teaches a safety shut-off system, but fails to specifically disclose circuitry for inactivating power when the level of current exceeds a predetermined value. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter assembly of Belef with such control circuitry, as similar shut-off systems to increase patient safety are well-known in the art, (see U.S. Patent No. 5,540,681 to Strul et al. (column 7, lines 47-62) for example).

4. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,398,755 to Belef et al. in view of U.S. Patent No. 5,921,956 to Grinberg et al.

With respect to claim 6, Belef teaches an interventional catheter assembly comprising an operating head coupled to a drive shaft and a drive assembly for rotation; a catheter system forming a lumen mounted for axial translation at a proximal end with

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a control pod and communicating at a distal end with the operating head as described above.

Belef fails to teach a torque selection feature.

Grinberg teaches a catheter assembly with a torque selection controlled by a control unit (114). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter assembly of Belef with the adjustable torque of Grinberg so that the surgeon has control over the catheter assembly (column 7, lines 49-62).

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,398,755 to Belef et al.

With respect to independent claim 1, Belef teaches an interventional catheter assembly (4) comprising: an operating head (32) coupled to a drive shaft and a drive assembly (22) for rotation and a catheter system forming a sealed lumen mounted for axial translation at a proximal end with a control pod (6) and communicating at a distal end with the operating head; and a control pod housing operational components for selectably rotating the operating head, wherein the control pod houses a drive motor operably coupled to the drive shaft and the drive motor is coupled to an actuator operable communication with the drive system, and wherein the actuator incorporates a switch that activates the drive system (column 4, line 35 to column 5, line 9).

Belef discloses the claimed invention except for teaching that the actuator is mounted on the catheter system distally to the control pod. It would have been obvious

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to one having ordinary skill in the art at the time the invention was made to place the actuating switch distally of the control pod, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

6. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,398,755 to Belef et al. in view of U.S. Patent No. 5,584,843 to Wulfman et al.

Belef teaches an interventional catheter assembly as described above, but fails to teach a guidewire brake.

Wulfman teaches an interventional catheter assembly with a guidewire brake (column 5, line 18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter assembly of Belef with the guidewire brake of Wulfman to control the movement of the guidewire (column 5, lines 14-19).

7. Claims 2, 3, 4, 5, 9, 10, 16, 17, 19, 24, 27, 28, 29, 32, and 58-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,398,755 to Belef et al. in view of U.S. Patent No. 5,921,956 to Grinberg et al., US 2002/0007190 to Wulfman et al., U.S. Patent No. 6,565,588 to Clement et al., and U.S. Patent No. 5,584,843 to Wulfman et al; and U.S. Patent No. 5,540,681 to Strul et al.

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Independent claims 1, 6, 18 and 56 are made obvious by the prior art cited above. The features found in dependent claims 2, 3, 4, 5, 9, 10, 16, 17, 19, 24, 27, 28, 29, 32, and 58-65 are also taught or made obvious by the cited references.

### ***Response to Arguments***

8. Applicant's arguments filed 11/25/2008 have been fully considered but they are not persuasive.

9. The Applicant argues that Belef, Wulfman and Clement fail to teach control circuitry to inactivate power when the current level is too high. The Examiner finds this limitation to be within the level of ordinary skill in the art, and is a well known safety feature.

10. With respect to claim 18, the Applicant argues only the arrangement of components of the operating system of the catheter. Again, the examiner finds that rearranging parts of the invention of Belef to be within the level of ordinary skill in the art.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia whose telephone number is (571) 270-5033. The examiner can normally be reached on Monday-Thursday 8:00am - 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786-9199 (IN USA OR CANADA) or (571) 272-1000.



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/Aarti Bhatia/

Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763